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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 120

[Docket No. 97N–0511]

RIN 0910–AA43

Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice; Availability of New Data and Information and Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to (*insert date 60 days after publication in the* **Federal Register**), the comment period for the proposal to require the application of hazard analysis and critical control point (HACCP) principles to the processing of fruit and vegetable juices and juice products (the juice HACCP proposal) that published in the **Federal Register** of April 24, 1998 (63 FR 20450). The agency is reopening the comment period for the juice HACCP proposal in order to receive comment and other information on four specific issues: internalization and survival of pathogens in produce used to produce juice, especially citrus fruit; application and measurement of the 5-log reduction standard; current methods used by juice processors to monitor the application of heat treatment to juice; and certain economic matters related to juice regulation. FDA is also announcing the availability of new data and other information about the safe processing of juice and juice products, and is requesting comment on the new data and other information.

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DATES: Written comments must be received by (*insert date 60 days after publication in the* **Federal Register**).

ADDRESSES: Submit written comments and requests for single copies of the transcripts to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Shellee Anderson, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5023.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 24, 1998 (63 FR 20450), FDA proposed regulations to ensure the safe and sanitary processing of fruit and vegetable juices. In addition, in the **Federal Register** of July 8, 1998 (63 FR 37030), FDA published a final rule requiring that juice products not specifically processed to destroy harmful bacteria (i.e., processed to achieve a 5–log (105) reduction in the most resistant pathogen of public health significance) bear a warning statement informing consumers of the potential risk of foodborne illness associated with the product (the warning statement rule). The compliance date for the warning statement rule was September 8, 1998, for apple juice and apple cider; the compliance date for juices other than apple juice or apple cider was November 5, 1998.

Interested persons were initially given until July 8, 1998, to comment on the HACCP proposal. On July 8, 1998 (63 FR 37057), in response to requests, the HACCP proposal comment period was extended to August 7, 1998. FDA subsequently reopened the comment period on December 17, 1998 (63 FR 69579) until January 19, 1999, to receive comments on data and other information that were presented at or developed as a result of two technical scientific workshops sponsored by FDA regarding implementation of the agency's warning statement requirement for fruit and

vegetable juices and juice products and to receive comments and other information regarding the application of the 5–log pathogen reduction standard.

As noted, in the HACCP proposal, FDA proposed to require that juice processors include in their HACCP plans control measures that will produce at least a 5-log reduction in the pertinent pathogen. The agency did not propose a specific intervention technology (e.g., pasteurization), but instead proposed a flexible 5-log performance standard that theoretically could be met through cumulative steps and, at least for some fruit (e.g., oranges), through surface treatments. In the preamble to the proposed rule, FDA stated that pathogens are not reasonably likely to be present in the interior of sound whole oranges or other citrus fruits, and further, that the acidic nature of citrus fruits may further inactivate any pathogens that may be present (63 FR 20450 at 20478). In the proposal, FDA noted that steps such as culling, washing, brushing, and sanitizing the surface of fruit, followed by extraction that minimized contact with the peel, could be used cumulatively to attain the 5-log reduction, as long as processors could validate the reduction under their HACCP systems.

Comments to the proposed rule, as well as new information available to FDA, have questioned the assumption that pathogens are not likely to be found in the interior of citrus fruit and have further suggested that surface treatment of fruit alone may not be adequate to ensure the safety of juice. In addition, FDA has undertaken research that suggests that, under certain conditions, pathogens could be internalized into citrus fruit and could survive once inside the fruit (Ref. 1). Specifically, the FDA studies show that the temperature differential between warm citrus fruit and cool wash water containing dye causes uptake of the dye into the fruit (Ref. 2). FDA believes that this dye study suggests that pathogens could likewise be drawn into the fruit through the stem scar or imperceptible cracks and holes if warm fruit is washed in cold water during preprocessing or possibly while the fruit is on the tree during a heavy rain storm. These susceptible fruits appear to be intact and would not necessarily be culled out and thus, could be processed into juice.

FDA has also reviewed the published literature and certain unpublished information relevant to pathogen infiltration and survival in produce and has summarized this information in a background document (Ref. 3). This information, in addition to data gathered by FDA (Ref. 1), suggests that there is potential for internalization of pathogens in apparently intact fruit. Based on this information, FDA has concerns that citrus fruit may not be impervious to penetration by pathogens, as was originally assumed in the proposed HACCP rule and the final labeling rule.

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture will soon announce a 3-day meeting (December 8 through 10, 1999) of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF); during days one and two of that meeting, NACMCF will focus on juice safety. FDA intends to provide the members of NACMCF with a copy of the summary document, Potential for Infiltration, Survival, and Growth of Human Pathogens within Fruits and Vegetables, as well as a report of the results of the recent FDA studies concerning the internalization and survival of microorganisms in citrus, Preliminary Studies on the Potential for Infiltration, Growth and Survival of *Salmonella enterica* serovar Hartford and *Escherichia coli* O157:H7 within Oranges, for their consideration prior to the December meeting. At the December meeting, FDA will be asking NACMCF to consider performance criteria for fresh juice, and specifically, to make recommendations about the efficacy of surface treatments in ensuring the safety of citrus juices.

II. Request for Comments

In order for FDA to make sound decisions regarding the application of HACCP principles to the processing of juice, the agency should have before it the most complete administrative record possible. To that end, FDA is requesting additional comment in four separate areas: (1) Internalization and survival of pathogens in produce used to produce juice, especially citrus fruit; (2) application and measurement of the 5-log reduction standard; (3) current methods used by juice processors to monitor the application of heat treatment to juice; and (4) certain economic

matters related to juice regulation. In addition, FDA is requesting comment on the new data and other information being added to the administrative record of this rulemaking.

First, concerning internalization and survival of pathogens, FDA is requesting comment, and supporting data or other information, on the following questions:

(1) One assumption underlying the HACCP proposal is that there is no internalization of pathogens in citrus fruit. Is this assumption valid?

(2) Is internalization of pathogens into citrus fruit theoretically possible?

(3) If internationalization of pathogens into citrus fruit is theoretically possible, is such internalization likely to result in a public health risk?

(4) If internalization does occur and it results in a public health risk, are there techniques to assure that internalization of pathogens does not occur? What are they?

Second, comments to the proposed HACCP rule requested that FDA clarify at what point in the production process a processor should begin to measure attainment of the 5–log pathogen reduction. In light of the new data and information on pathogen internalization and survival, FDA's current view is that for any juice made from fruit for which there is a potential for pathogens to be internalized, measurement of the 5–log reduction must begin where preventive treatment has intimate contact with pathogens. This means that the 5–log reduction must be achieved after the juice has been extracted. Accordingly, in terms of the application of the 5–log reduction, FDA requests comment on the following:

(1) FDA's current view is that the 5-log pathogen reduction must begin where the preventative treatment has intimate contact with the pathogens. FDA is particularly interested in any data or other information about scientifically validated procedures for a 5–log reduction that address FDA's concerns about pathogen internalization and that begin earlier in the process than the juice expression step.

(2) The ability of processors to achieve the desired level of public health protection if processors: (a) Use cumulative steps that are separated in time or location, or (b) do not package product immediately after attaining the 5–log reduction.

(3) For firms producing fresh juice, the costs and economic feasibility of achieving a 5-log pathogen reduction using the approach reflected in FDA's current thinking.

(4) The benefits to processors of using this enhanced 5-log pathogen reduction approach in terms of improved shelf-life or other any benefit.

Third, FDA is aware that the majority of juice processors already apply some sort of heat treatment to the juice that they produce. Under a HACCP system, the application of heat is a critical control point (CCP) in terms of controlling microbiological hazards. FDA requests comments that describe the monitoring methods that juice processors currently use to assure that the heat treatment is adequately delivered so as to control pathogens.

Fourth, FDA also specifically requests comment on several economic issues, as follows:

(1) The agency is aware that some consumers prefer to consume raw (i.e., unprocessed) juice. FDA requests comment from these consumers concerning how much they would be willing to pay for a gallon of raw juice. FDA also requests information from raw juice processors on the percent of annual profit that firms derive from the sale of raw juice.

(2) The agency developed a preliminary regulatory impact analysis and a small entity analysis that estimate benefits and costs associated with the HACCP proposal. These analyses were published in the **Federal Register** of May 1, 1998 (63 FR 24254). FDA requests comment on impacts, costs, and benefits on businesses with fewer than 500 employees.

(3) FDA requests comment on the ways in which processors that have already implemented HACCP have done so in a manner that is different from the provisions of the proposed rule.

Finally, as noted above, FDA has prepared a summary of certain data and information regarding internalization and survival of pathogens in produce. The agency has also prepared reports of the agency's recent research. FDA is announcing the availability of the following: (1) Two documents summarizing new data on internalization and survival of microorganisms in citrus (Refs. 1 and 2); and (2) a review of published and unpublished information on internalization and survival of microorganisms in fruits and vegetables (Ref. 3). FDA is also announcing the availability for

public comment of the transcripts from a July 15 to 16, 1999, FDA-sponsored technical scientific workshop on apple cider.

To be considered, written comments must be received by (*insert date 60 days after publication in the* **Federal Register**), by the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Walderhaug, M. O., S. Edelson-Mammel, A. DeJesus, B. S. Eblen, A. J. Miller, and R. L. Buchanan. ''Preliminary Studies on the Potential for Infiltration, Growth and Survival of *Salmonella enterica* Serovar Hartford and *Escherichia coli* O157:H7 Within Oranges.'' U.S. Food and Drug Administration, November 8, 1999.

2. Merker, R., S. Edelson-Mammel, V. Davis, R. L. Buchanan. ''Preliminary Experiments on the Effect of Temperature Differences on Dye Uptake by Oranges and Grapefruit. U.S. Food and Drug Administration, November 4, 1999.

3. Potential for Infiltration, Survival, and Growth of Human Pathogens within Fruits and Vegetables, U.S. Food and Drug Administration, November 3, 1999.

Dated: 11 16-99

November 16, 1999

Margaret M. Dotzel
Acting Associate Commissioner
for Policy

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